DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 29, 2015

Dunamis, LLC
% Mr. Robert O. Dean
Lexamed
705 Front Street
Toledo, Ohio 43605

Re: K150327
Trade/Device Name: Dunamis Force DFX Suture
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture.
Regulatory Class: Class II
Product Code: GAT
Dated: March 25, 2015
Received: March 31, 2015

Dear Mr. Dean:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Dunamis Force DFX Suture

Indications for Use *(Describe)*
The Dunamis Force DFX Sutures, Polyethylene Non-Absorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues including use in cardiovascular surgeries and the use of allograft tissue for orthopaedic surgeries.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510K Summary – Rev. 2

1. **Submitter:** Dr. Prithvi Raj Chavan
Dunamis, LLC.
693 Sherling Lake Rd.
Greenville, AL. 36037
(p) 731-217-2533
Email: dr.raj76@gmail.com

2. **Date Prepared**: 04/21/15

3. **Name of Device:**
   - Proprietary Trade Name: Dunamis Force DFX Suture
   - Common Name: Suture, Polyethylene Synthetic Non-Absorbable Surgical Suture
   - Classification Name: Non-absorbable poly (ethylene terephthalate) surgical suture
   - Code: GAT
   - Regulation:878.5000

4. **Identification of the legally marketed device (predicate):**
Teleflex Force Fiber Polyethylene Non-Absorbable Surgical Sutures, K063778.

5. **Description of the device**: The Dunamis Force DFX Sutures are sterile single use sutures are used in approximation and/or ligation of soft tissues, including use in cardiovascular surgeries and the use of allograft tissue for orthopaedic surgeries. The technical design configuration for both USP Size 2 and Size 5 are as follows:

   USP Size 2 (metric 5)
   White/Blue Co-braid - Ultra High Molecular Weight Polyethylene (UHMWPE) Suture USP Size 2 (oversized) x 36" length, single armed HC-5 needle.
   Packaged 1(one) strand per pouch, 12 pouches per box, sterile.

   USP Size 5 (metric 7)
   White/Blue Co-braid - Ultra High Molecular Weight Polyethylene (UHMWPE) Suture USP Size 5 (oversized) x 36" length, single armed HS48 needle.
   Packaged 1(one) strand per pouch, 12 pouches per box, sterile

   Materials:
   Co-Braid of UHMWPE and Blue Monofilament Polypropylene Non-absorbable Surgical Suture. Sutures meets USP requirements except for diameter.
   Polymer/Colorant: Ultra High Molecular Weight Polyethylene (white): None
   Polypropylene (blue): [phthalocyaninato (2-)] copper with a concentration not to exceed 0.5% by weight.

6. **Indications for Use:** The Dunamis Force DFX Sutures, Polyethylene Non-Absorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues including use in cardiovascular surgeries and the use of allograft tissue for orthopaedic surgeries.

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7. **Comparison of Technological Characteristics**: The Dunamis Force DFX Sutures are contract manufactured for Dunamis by Teleflex Medical to the same specifications for the Force Fiber sutures cleared in K063778; therefore, the device characteristics are identical to the predicate. The only differences between the Dunamis device and the predicate device are the brand name, part number, and "manufactured for" indication on the product labeling.

8. **Description of Device Design and Test Methods:** Dunamis LLC. has established a contract manufactured product specifications that has been accepted by Teleflex Medical which documents and secures the product configuration and required test methods to assure the device is equivalent in performance and to all the elements of Teleflex 510k K063778.

   USP Size 2 (metric 5)
   White/Blue Co-braid - Ultra High Molecular Weight Polyethylene (UHMWPE) Suture USP Size 2 (oversized) x 36" length, single armed HC-5 needle.
   Packaged 1(one) strand per pouch, 12 pouches per box, sterile.

   USP Size 5 (metric 7)
   White/Blue Co-braid - Ultra High Molecular Weight Polyethylene (UHMWPE) Suture USP Size 5 (oversized) x 36" length, single armed HS48 needle.
   Packaged 1(one) strand per pouch, 12 pouches per box, sterile

   Materials:
   Co-Braid of UHMWPE and Blue Monofilament Polypropylene Non-absorbable Surgical Suture. Sutures meets USP requirements except for diameter.
   Polymer/Colorant: Ultra High Molecular Weight Polyethylene (white): None
   Polypropylene (blue): [phthalocyaninato (2-)] copper with a concentration not to exceed 0.5% by weight.

   Performance Testing:
   Dunamis has established contract manufactured product specifications with Teleflex Medical that documents the product configuration and required test methods to assure the device is identical in performance and to all the elements of Teleflex 510(k) K063778. Because the sutures are manufactured to the same specifications as those cleared in K063778, data provided in K063778 may be leveraged to support equivalence, including testing in accordance to the USP for non-absorbable sutures, biocompatibility testing performed in accordance with ISO 10993-1, and stability testing. No additional testing was performed on the contract-manufactured product.

9. **Conclusions**: The Dunamis Force DFX Sutures are identical to the predicate Force Fiber sutures cleared in K063778 with respect to indications for use, materials, design, and manufacturing processes. The sutures are contract manufactured for Dunamis by Teleflex to the same product specifications cleared in K063778. Therefore, the Dunamis Force DFX Sutures are substantially equivalent to the Force Fiber sutures cleared in K063778.